DOWD, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Jamie Lynn Lorenzi,	)	
	)	CASE NO. 4:06 CV 1985
Plaintiff(s),	)	
	)	
v.	)	MEMORANDUM OPINION
	)	
Pfizer Inc.,	)	(Resolving Doc. Nos. 21, 35, 36)
	)	
Defendant(s).	)	
	)	

Before the Court is the motion for summary judgment of defendant, Pfizer Inc. ("Pfizer") (Doc. No. 21, as supplemented by Doc. No. 28), plaintiff's memorandum in opposition (Doc. No. 30), and Pfizer's reply (Doc. No. 33).[1] For the reasons discussed below, the motion is granted.

I. BACKGROUND

On July 12, 2006, plaintiff Jamie Lorenzi filed an action against Pfizer in Mahoning County Court of Common Pleas. Pfizer properly removed the action to this Court on the basis of diversity jurisdiction.

[1] Without leave of Court, plaintiff also filed a sur-reply, which defendant moved to strike. Plaintiff then moved for leave to file a sur-reply; defendant filed its opposition. The Court has taken the sur-reply (Doc. No. 34) into consideration. Therefore, defendant's motion to strike (Doc. No. 35) is denied and plaintiff's motion for leave to file (Doc. No. 36) is denied as moot.

The Complaint alleges that plaintiff began receiving Depo-Provera Contraceptive Injection ("DPCI")[2] on or about March 1997 and continued every three months thereafter until January 2005. The injections were administered by personnel at the Planned Parenthood office in Youngstown, Ohio. There is no dispute that defendant and/or its successor manufactured and distributed the drug.

On October 6, 2004, for no apparent medical reason,[3] plaintiff underwent a bone mineral density scan, which revealed that she had what would be considered low bone mineral density ("BMD"). Plaintiff asserts that her low BMD, which she characterizes as an injury, was caused by Depo-Provera and that defendant failed to give adequate warnings that bone loss was a possible side effect of using the contraceptive. Plaintiff's deposition reveals that she is currently 30 years old, having been born in 1977.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56 . When

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[2] The drug, depot-medroxyprogesterone acetate, is typically abbreviated "DMPA," particularly in some of the medical literature cited herein. In this opinion, the relevant drug is referred to variously as DPCI, DMPA, and Depo-Provera. Therefore, although there may actually be some technical difference among the three, for purposes of this opinion, all three uses are intended to refer to the drug about which plaintiff complains in this lawsuit.

[3] At her deposition, plaintiff, who is employed by Mahoning County Medical Group, testified that she got the bone scan because "[i]t was a new machine . . . and just about everyone in the office had one [the scan]." Lorenzi Dep. at 40 (Doc. No. 22-2). It appears that they may have simply been practicing the use of the new machine. Defendant's expert, Dr. Licata, whose expert report is discussed in more detail below, stated that the test was "unfortunate and should not have been done because the interpretation of her values is not the same as an older individual's." (Doc. No. 28-2, at 2). Based on her date of birth, plaintiff was approximately 27 years old when she had the bone scan.

considering a motion for summary judgment, "the inferences to be drawn from the underlying facts contained in [affidavits, pleadings, depositions, answers to interrogatories, and admissions] must be viewed in the light most favorable to the party opposing the motion." U.S. v. Diebold, Inc., 369 U.S. 654, 655 (1962). However, the adverse party "may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986).

The Rule requires the nonmoving party who has the burden of proof at trial to oppose a proper summary judgment motion "by any of the kinds of evidentiary material listed in Rule 56(c), except the mere pleadings themselves[.]" Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). General averments or conclusory allegations of an affidavit do not create specific fact disputes for summary judgment purposes. See Lujan v. National Wildlife Federation, 497 U.S. 871, 888-89 (1990). Nor may a party "create a factual issue by filing an affidavit, after a motion for summary judgment has been made, which contradicts . . . earlier deposition testimony." Reid v. Sears Roebuck & Co., 790 F.2d 453, 460 (6th Cir. 1986) (citing Biechell v. Cedar Point, Inc., 747 F.2d 209, 215 (6th Cir. 1984)); but see Baer v. Chase, 392 F.3d 609, 623-26 (3d Cir. 2004) (noting that a so-called "sham" affidavit need not be disregarded if there is "independent evidence in the record to bolster [the] otherwise questionable affidavit"). Further, "'[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.'" Street v. J.C. Bradford & Co., 886 F.2d 1472, 1477 (6th Cir. 1989) (quoting Anderson v. Liberty Lobby, 477 U.S. at 252).

In sum, "[t]he inquiry performed is the threshold inquiry of determining whether there is the need for a trial -- whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, 477 U.S. at 250. Put another way, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. See also Wexler v. White's Fine Furniture, Inc., 317 F.3d 564, 578 (6th Cir. 2003) ("[t]he conflicting proof and the inferences that can be drawn therefrom raise genuine issues of material fact that preclude the grant of summary judgment").

III. DISCUSSION

A. Some Background on Depo-Provera

Depo-Provera was first approved by the Food and Drug Administration ("FDA") for non-contraceptive use in 1960. (See Doc. No. 22-7). It has been used around the globe as a contraceptive for about 30 years, but the FDA did not approve it for such use in this country until October 1992. (Doc. No. 22-8). Marketing of the drug in the United States began in 1992. From 1992 until 2004, the Package Insert gave the following warning:

> 2. *Bone Mineral Density Changes*
>
> Use of DEPO-PROVERA Contraceptive Injection may be considered among the risk factors for development of osteoporosis. The rate of bone loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall.

(Hughes Aff., Doc. No. 22-4, p. 14).

During that same time frame, the additional Patient Brochure distributed for discretionary use by physicians in advising patients stated, in relevant part:

> **Risks of Using DEPO-PROVERA Contraceptive Injection**
>
> 2. *Bone Mineral Changes*
>
> Use of DEPO-PROVERA Contraceptive Injection may be associated with a decrease in the amount of mineral stored in your bones. This could increase your risk of developing bone fractures. The rate of bone mineral loss is greatest in the early years of DEPO-PROVERA Contraceptive Injection use but, after that, it begins to resemble the normal rate of age related bone loss.

(Id., p. 19).

According to the National Osteoporosis Foundation website,[4] the World Health Organization defines "osteoporosis" based on bone density levels as follows:

Normal:	Bone Density is within 1 SD (+1 or -1) of the young adult mean.
Low Bone Mass: (Osteopenia)	Bone density is 1 to 2.5 SD below the young adult mean (-1 to -2.5 SD).
Osteoporosis:	Bone density is 2.5 SD or more below the young adult mean (> -2.5 SD).
Severe osteoporosis:	Bone density is more than 2.5 SD below the young adult mean and there has been one or more osteoporotic fractures.

The website further explains, in easily understandable language:

> Your BMD is compared to two norms, "young normal" and "age-matched." Young normal, known as your T-score, compares your BMD to optimal or peak density of a 30-year old healthy adult and determines your fracture risk, which increases as BMD falls below young-normal levels.

[4] http://www.nof.org/osteoporosis/bmdtest.htm (last visited Oct. 22, 2007).

> Age-matched, known as your Z-score, compares your BMD to what is expected in someone your age and body size. Among older adults, however, low BMD is common, so comparison with age-matched norms can be misleading.
>
> The difference between your BMD and that of a healthy young adult is referred to as a standard deviation (SD). As outlined in the World Health Organization's diagnostic categories, individuals whose T-score is within one standard deviation of the "norm" are considered to have normal bone density. Scores below the "norm" are indicated in negative numbers. For example, a score from -1 to -2.5 SD below the norm indicates low bone mass, or osteopenia, and a score of more than -2.5 SD below the norm is considered a diagnosis of osteoporosis. For most BMD tests, -1 SD equals a 10-12 percent decrease in bone density.

Although there is general agreement about the definition of "osteoporosis," it is more difficult to decide what any individual's BMD actually means. In 2002, Dr. Carolyn Westhoff summarized the research as follows in the Journal of Reproductive Medicine:

> Impaired bone metabolism in women on DMPA [Depo-Provera] remains controversial. While the majority of data do associate DMPA with a modest loss of bone density, this finding has not been consistent. In studies that have shown a relationship, there has been no relationship with duration of therapy. No study has associated DMPA with any measurable increased risks from loss of bone density. A large number of variables affecting bone density prior to menopause, such as life-style and genetic risk, complicate efforts to isolate the effect of a single variable. The possible but unproven fracture risk posed by the types of modest bone loss recorded in some studies of DMPA should be weighed against the immediate benefits from prevention of unwanted pregnancy.

(Carolyn Westhoff, *Bone Mineral Density and DMPA*, 47 J.Reprod.Med. 795, 799 (2002) (Doc. 22-10, p. 4)).

In 1992, when the FDA approved use of Depo-Provera as a contraceptive in the United States, the Advisory Committee recommended that the company conduct a post-marketing study to better understand the relationship between the drug and BMD. This study commenced in 1994. In 2004, the results submitted to the FDA showed that, during five years of use, women

using the contraceptive had lower bone density on average than non-users and that the difference was statistically significant, but that, upon cessation of use, the average bone density of users recovered. Since the study had encompassed only two years of post-use data, no conclusion was reached as to whether bone density would fully recover and, if so, how long full recovery might take. (Andrew M. Kaunitz, et al., *Bone mineral density in women aged 25-35 receiving depot medroxyprogesterone acetate: recovery following discontinuation*. (Doc. No. 22-9, p. 9).

As a result of this study, the Package Insert was revised, with FDA approval, to contain a "Black Box Warning" as follows:

> **Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.**
>
> **It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture later in life.**
>
> **Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control medications are inadequate (see WARNINGS).**

(Doc. 22-11). The revised Package Insert included a detailed discussion of the Phase IV study results. (Id.). Physicians were also advised of the change in package labeling. (See Doc. No. 22-12).

Even though this black-box was added to the package, there was criticism of its warning by the medical community. In reviewing the literature on Depo-Provera and BMD, the American College of Obstetricians and Gynecologists (ACOG) noted:

> Many studies have observed bone mineral density declines in current users of DMPA, which is seen as a surrogate marker for future osteoporosis and fracture. None of these found evidence of osteoporosis or fractures in DMPA users. Two cross-sectional studies found that years after DMPA discontinuation, bone mineral density was similar in former and never users of DMPA. A large U.S. prospective study of adult DMPA users found that within 30 months following DMPA discontinuation, bone mineral density of the spine and hip was similar to that of nonusers.
>
> * * *
>
> . . . The bone mineral density trends seen with DMPA seem to be similar to those noted during lactation in that no long-term decrease occurs.
>
> Given the above observations, skeletal health concerns should not restrict use of DMPA in adult women. . . . Regardless of age, short or long-term use of DMPA in healthy women likewise should not be considered an indication for DXA or other tests that assess bone mineral density.

(Doc. No. 22-13, at p. 12, internal citations omitted).

B. Plaintiff's Use of Depo-Provera

Plaintiff's first use of DPCI was on March 25, 1997 at Planned Parenthood of Mahoning Valley. She was 25 years old, and had given birth about one month earlier. (Lorenzi Dep. at 8-9, Doc. No. 22-2). Plaintiff chose this form of contraception because, with an infant to care for, "it seemed to be the easiest and the best choice at the time." (Id. at 10). In addition, she had been advised that it would relieve some of the pain and severity of her menstrual periods.

On the day of her first injection, plaintiff signed a very detailed 4-page document entitled "Request for Examination, Treatment, and Injection of Depo Medroxyprogesterone Acetate (DMPA: Depo-Provera) for Contraception." (Lorenzi Dep., Exh. A, Doc. No. 22-2, p. 33). Among the statements she individually initialed on the 4-page form were the following:

> I have received from Planned Parenthood a brochure containing information on the use, effectiveness, and medically recognized benefits and risks of the available birth control methods and devices. I have read the brochure, understand it, and have had all my questions answered.
>
> I have been given the FDA-approved DMPA Patient Labeling pamphlet provided by the DMPA manufacturer. I know that I should read it and ask questions about anything I do not understand.

(Doc. No. 22-2, at 33; Lorenzi Dep. at 17-18). At her deposition, plaintiff confirmed that she had received, read and understood both the Planned Parenthood brochure and the DMPA Patient Labeling pamphlet. (Lorenzi Dep. at 23-28).

Except for a hiatus of about eighteen months sometime between 1997 and 1999 when she was not sexually active and, therefore, voluntarily decided not to expend any funds on contraception (Lorenzi Dep. at 12, 29), plaintiff continued to receive Depo-Provera injections every three months until January 2005.[5] Each time plaintiff received an injection, she was provided with the Patient Brochure for the product, a fact she admits. (See Lorenzi Dep. at 94).

In October 2004, the medical group for whom plaintiff worked got a new machine that measured bone mineral density. All the employees were offered a free scan and plaintiff had one done. There was no medical reason to do so and no physician had ordered the scan. She was about 27 years old at the time. Plaintiff's scan results showed T-scores of -1.6 in the spine, -2.3 in the hip, and -1.1 in the forearm. Under WHO guidelines cited above, these scores are within the osteopenia range. (Lorenzi Dep. at 39-40, 45-46). However, it must be noted that the

[5] On April 20, 1999, when plaintiff resumed the Depo-Provera injections after the hiatus, she once again had to sign the 4-page consent document. (See Doc. No. 22-2, pp. 29-32).

"young normal" guideline of WHO is based on a person who is 30 years old; plaintiff was only 27.

Although she knew her scores were low, she never sought medical advice about the scan until February 2005, when she saw her own physician, Dr. Zeno. He ordered blood tests to determine whether she had any condition that would cause low BMD. (Lorenzi Dep. at 50-51). Plaintiff also consulted with Dr. Toth, a rheumatologist, who apparently concurred with Dr. Zeno's diagnosis of osteopenia. This was in May of 2005.

Plaintiff has no idea whether her BMD readings in 2004 were lower than they had been prior to taking Depo-Provera because she had never had any kind of baseline scan to use for comparison purposes. At her deposition, when questioned by defendant's counsel, she testified as follows:

> Q. . . . Before October of 2004 did you have any other kind of evaluation or test to determine what your bone mineral density was?
>
> A. No.
>
> Q. Has anyone told you that your bone mineral density was much better before your Depo-Provera use that it was in October of 2004?
>
> A. No.

(Lorenzi Dep. at 52).

Plaintiff claims that her low BMD is an "injury" for which she can recover in damages. However, Dr. DeSalvo, plaintiff's own physician at Planned Parenthood, testified at his deposition that, without a baseline BMD measurement for comparison purposes, one cannot

know whether her BMD is naturally low or was caused or aggravated by the Depo-Provera, especially given the fact that plaintiff has other risk factors for low BMD, namely a small frame and a history of smoking. In fact, at his deposition, Dr. DeSalvo testified that "to say she has osteopenia as a result of anything I think is not medically supported, other than this just could be her genetic predisposition." (DeSalvo Dep. at 37-38). He further testified as follows:

> Q. As a medical doctor, Dr. DeSalvo, if a patient of yours does not have a history of Depo-Provera use but has a reduced bone mineral density, do you have an opinion that she has been injured?
>
> * * *
>
> A. [T]here's no injury. Just to have low bone mineral density means nothing. Osteopenia is not osteoporosis. And osteopenia is not a disease; it's a statistical score. And this statistical score is well within the realm of patients living in normally distributed populations. So somebody who scores a T-score, you know, at 1.6 standard deviations of the mean tells me that she's not within the first 68 percent of the population, but she's definitely within the next, in the 95 percent of the population, and she's probably, you know, included within 75 percent of the population. So her [sic] and 75 percent of the population have a T-score of 1.6.

(DeSalvo Dep. at 29-30).

Since she had the BMD scan in 2004, plaintiff has consulted with at least two additional physicians and no one has prescribed treatment beyond a recommendation to increase her calcium intake, quit smoking and start exercising. She has not quit smoking and is unable to say that she engages in much exercise much beyond some "on and off" stretching two or three times a week. (Lorenzi Dep. at 67-68).

C. Analysis

In her complaint, plaintiff claims that defendant failed to give adequate warnings regarding the dangers of Depo-Provera with respect to bone mineral density.

Since this is a diversity action, the Court applies the law of the forum state. Product liability claims in Ohio are governed by the Ohio Products Liability Act ("OPLA"), Ohio Rev. Code §§ 2307.71 - .80. The statute establishes the threshold for an adequate warning. A warning is inadequate if, when it left the manufacturer's control, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A)(1). See also Seley v. G.D. Searle & Co., 67 Ohio St.2d 192, 198 (1981) ("a warning is 'adequate' . . . where, under all the circumstances, it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist.")

OPLA also makes clear that a manufacturer's duty to warn a consumer regarding the dangers of a drug that requires a prescription is discharged where the physician receives adequate warning. Ohio Rev. Code § 2307.76(C); Howland v. Perdue Pharma L.P., 104 Ohio St.3d 584 (2004).

There is no question that defendant gave warnings to both the physician and plaintiff. These warnings are quoted in an earlier section of this opinion and are repeated here for convenience. From 1992 to 2004, the warning given to physicians was as follows:

> 2. *Bone Mineral Density Changes*
>
> Use of DEPO-PROVERA Contraceptive Injection may be considered among the risk factors for development of osteoporosis. The rate of bone loss is greatest in the early years of use and then subsequently approaches the normal rate of age related fall.

(Hughes Aff., Doc. No. 22-4, p. 14). The additional Patient Brochure distributed for discretionary use by physicians in advising patients stated, in relevant part:

> **Risks of Using DEPO-PROVERA Contraceptive Injection**
>
> 2. *Bone Mineral Changes*
>
> Use of DEPO-PROVERA Contraceptive Injection may be associated with a decrease in the amount of mineral stored in your bones. This could increase your risk of developing bone fractures. The rate of bone mineral loss is greatest in the early years of DEPO-PROVERA Contraceptive Injection use but, after that, it begins to resemble the normal rate of age related bone loss.

(Id., p. 19). Following the so-called "Phase IV Study," the Package Insert was revised in 2004, with FDA approval, to contain a "Black Box Warning" as follows:

> Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.
>
> It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture later in life.
>
> Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control medications are inadequate (see WARNINGS).

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(Doc. 22-11).

The Court concludes that these warnings meet the threshold test for adequacy set forth in the statute and interpreted by case law. Any user of this drug who read these warnings would have been informed of the risks relating to bone loss. In fact, plaintiff herself admitted at her deposition that she read the patient labeling and other warnings, even though, at the time of her deposition, she had no independent recollection about what was contained in those labels or warnings. She also acknowledged that she knows (and knew back when she was receiving the drug) that all drugs entail risks.

Even if the warnings were inadequate, which they were not, plaintiff must also establish a causal link between the product and plaintiff's injury. Seley, 67 Ohio St.2d at 200. Plaintiff cannot meet this burden as established by the testimony and expert reports of various physicians.[6]

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[6] There is disagreement among the parties as to whether the various doctors are or are not "experts," which, in their view, assigns value to their opinions. The treating physician for whom no expert report is supplied is not permitted to go beyond the information acquired or the opinion reached as a result of the treating relationship to opine as to the causation of any injury, or to give an opinion regarding the view of any expert called by the defendant. See, e.g., Hawkins v. Graceland, 210 F.R.D. 210 (W.D. Tenn. 2002). The Hawkins court noted, at page 211:

> . . . Written reports are not required of all experts [by Rule 26(a)(2)(B)], but only those "who are retained or specially employed to provide such testimony in the case or whose duties as an employee of a party regularly involve the giving of such testimony." Fed.R.Civ.P. 26 advisory committee's note (1993). As the Advisory Committee observed, "[a] treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report." Id. A treating physician is not considered an "expert" for purposes of Rule 26 simply by virtue of his or her expertise. Fisher v. Ford Motor Co., 178 F.R.D.

(continued...)

In the first place, plaintiff is absolutely unable to prove that her low BMD is an *injur*y in any legal sense and, in the second place, even if the Court were to assume plaintiff suffered an injury, she is unable to establish any causal connection between that injury and Depo-Provera.

Plaintiff asserts that her "osteopenia" is an injury. In support of that claim, she cites the deposition testimony[7] of a treating rheumatologist, Dr. Mary B. Toth,[8] who had advised plaintiff that, in her opinion, plaintiff's low BMD was due to the use of Depo-Provera. That, however, is

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[6] (...continued)
195, 197 (N.D.Ohio 1998). The physician is not categorized as an expert witness "if he or she testifies about observations based on personal knowledge, including the treatment of the party." Davoll v. Webb, 194 F.3d 1116, 1138 (10th Cir. 1999). Thus, "to the extent that a treating physician testifies only to the care and treatment of the patient, the physician is not considered to be a 'specially employed' expert and is not subject to the written report requirements of Rule 26(a)(2)(B)." Salas v. United States, 165 F.R.D. 31, 33 (W.D.N.Y. 1995); see also Sullivan v. Glock, Inc., 175 F.R.D. 497, 501 (D.Md. 1997) ("[t]o the extent that the source of the facts which form the basis for a treating physician's opinions derive from information learned during the actual treatment of the patient--as opposed to being subsequently supplied by an attorney involved in litigating a case involving the condition or injury--then no Rule 26(a)(2)(B) statement should be required"); Brown v. Best Foods, 169 F.R.D. 385, 387 (N.D.Ala. 1996) (same); Wreath v. United States, 161 F.R.D. 448, 450 (D.Kan. 1995) (same). "However, when the doctor's opinion testimony extends beyond the facts disclosed during care and treatment of the patient and the doctor is specially retained to develop opinion testimony, he or she is subject to the provisions of Rule 26(a)(2)(B)." Salas, 165 F.R.D. at 33. Thus, the application of the Rule 26 disclosure requirements depends on the substance of the treating physician's testimony rather than his or her status. See Washington v. Arapahoe County Dep't of Soc. Servs., 197 F.R.D. 439, 442 (D.Colo.2000).

[7] Plaintiff did not supply a copy of the deposition and her quotations had no citation to the actual deposition pages. Apparently, the Court is supposed to take her word for it that the doctor testified in the manner she claimed. Fortunately, the *defendant* submitted copies of both treating physicians' depositions (Drs. Toth and Zeno) with its reply brief.

[8] After plaintiff had gotten the BMD scan at her workplace, she later took the results to her personal physician, Dr. Joseph Zeno, who referred her to a specialist, Dr. Toth.

not dispositive as to whether osteopenia is an injury in the legal sense of the term. Dr. Anthony DeSalvo, the Medical Director of Planned Parenthood at all relevant times, testified that osteopenia is no more than a statistical indicator, not a disease. (DeSalvo Dep. at 30). Dr. Zeno, plaintiff's primary care doctor testified that osteopenia is "is a diagnosis, not a disease." (Zeno. Dep. at 22, Doc. No. 33-2). Dr. Toth's testimony actually suggested the same. When asked at her deposition whether osteopenia is a disease, she stated:

> A. I don't know how you would classify osteopenia. It's between normal and osteoporosis. It's a tendency towards osteoporosis. Is it a disease entity in and of itself? I don't know.

(Toth Dep. at 30, Doc. No. 33-3).

Defendant's expert, Dr. Angelo A. Licata, a clinical endocrinologist at the Cleveland Clinic who specializes in calcium and bone disorders, indicated in his expert report as follows:

> [Osteopenia] means low amount of bone mass. The preferable term used today is low bone density. Osteopenia and "low bone density" are not diseases. Without other health problems, it does not imply a great deal about future fracture risk.

(Doc. No. 28-2, at p. 4). At his deposition, he testified that diminished bone mineral density "isn't necessarily synonymous with increased fracture risk." (Licata Dep. at 26).

Dr. Licata pointed out in his report that it was unfortunate that plaintiff had the BMD test performed "for no discernible medical reason . . . because the interpretation of her values is not the same as an older individual's." Id. at 2. With respect to plaintiff's alleged "bone loss," given that she was 27 when she was tested and the "young normal" bone density is measured at age 30, he opined:

> The plaintiff alleges bone loss from her drug therapy based upon the negative result she obtained from her BMD test. Bone loss implies a direction of change --

> a decrease from a prior baseline value. I have seen no such prior value to support this contention, so loss is difficult to prove. It is possible her first measure value reflected her best possible bone mass, her peak mass that resulted from influences on bone growth during puberty. There are several reasons why she may have had a low peak bone mass or a low T-score when she was first tested. She is female and Caucasian. She smoked tobacco products as a teenager. She has a small stature. Her puberty (menarche) started later than the average, giving the skeleton less time to respond to hormonal stimulation. Her exercise habits may not have been optimal. Her diet may not have been adequate in calcium and Vitamin D.

Id. at 3. In other words, it is impossible to establish causation from that one single low BMD test result. Even Dr. Toth, when pressed on the issue of causation, could not say for sure that there was a link with Depo-Provera use.

> Q. Do you have an opinion as to whether she suffered a loss of bone density as a result of Depo-Provera?
>
> A. I do not know what her bone density was prior to her starting the Depo-Provera, so I cannot say with absolute certainty that the Depo-Provera caused her low bone density; but there were no other causes that I could see at that time for her having a bone mineral density less than the third percentile for her age.

(Toth Dep. at 14, Doc. No. 33-3).

Dr. Licata also opined that, even if one were to assume the Depo-Provera caused bone loss in the plaintiff, one would have to ask *how much*. He stated:

> About 10-15% loss of bone mass corresponds to about one standard deviation decline in T-score. Studies indicate about a 1.0% per year decline in BMD in users of DPCI. The worst T-score value recorded for the plaintiff is -2.3 standard deviations. In order for the drug alone to produce this T-score, it must have caused a minimal bone loss of about 23 percent. Based on the average yearly decline in BMD studies of the drug, the plaintiff could not have developed the estimated lost of 23 percent from drug alone. She must have had a T-score before her use of the drug that was already negative. In other words, most of her negative T-score predated her drug use.

Id. at 3-4. Dr. Licata also noted that even if Depo-Provera caused some amount of bone loss, "[n]early complete recovery should occur after discontinuing it." Id. at 4. Since plaintiff's bone density did not return to a T-score closer to the mean, it is likely that "plaintiff's initial bone mass value may represent her actual peak bone mass and [did] not represent any effect of the drug." Id. at 5.

At his deposition, when questioned by plaintiff's counsel regarding a correlation between low BMD and risk of fracture, Dr. Licata differentiated between younger women and postmenopausal women in their 60's. He stated:

> A. . . . [I]t has to do with the fundamental structure of the bone. The architecture of the bone in somebody that age [over the age of 65] tends to be much deteriorated. Microscopic architecture this is. Such that when a person imposes certain loads on them or activities of daily living, the bone can't sustain that particular force and they break with very, very little trauma or injury. That's primarily the issue of risk when we speak of that age group.
>
> When you start talking about people below that age group, they may have the same bone density as somebody who's 70 but the bone structure, the bone quality, and the micro architecture is not deteriorated to the same degree. And the scientific studies have shown for years that the fracture risk for somebody who's 20, 25, 30, 35 who may have a bone density measurement the same as somebody whose [sic] aged 65, 70 and above, that younger person does not have susceptibility to breaking bones as that older person has despite what the density is saying.
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> * * *
>
> And that turns out to be a major reason for the distinction between the risk of fractures at one age and the risk of fractures at another age, despite the fact that the density may be similar.

(Licata Dep. at 19-20, Doc. No. 28-3).

Plaintiff is unable to show a current or future injury and, even assuming that she were able to establish injury, she is unable to show any causal link to her use of Depo-Provera.

IV. CONCLUSION

For the reasons discussed above, defendant is entitled to summary judgment and the same shall be granted.

IT IS SO ORDERED.

October 24, 2007
Date

s/ David D. Dowd, Jr.
David D. Dowd, Jr.
U.S. District Judge